SFDA Deputy Commissioner Wu Zhen meets Director-General of Public Health of the Netherlands Ministry of Health, Welfare and Sport

On June 21, 2011, Wu Zhen, Deputy Commissioner of SFDA, met with the visiting Paul Huijts, Director-General of Public Health of the Ministry of Health, Welfare and Sport of the Netherlands, and his entourage. Both sides exchanged opinions on the new version of Good Manufacturing Practice (GMP) for Pharmaceutical Products of China, the pharmacovigilance of Britain and how to deepen the cooperation under the framework of the Memorandum of Understanding in the future.

(May 24, 2011)

Director General Wang Baoting introduced in a simple and creative manner the profundity of the development process, major challenges and tasks of China's medical device supervision and administration, as well as latest developments of the Revision of "Regulations for Supervision and Administration of Medical Devices".

Director General Wang Baoting stated that, compared with developed countries, there is a good deal of discrepancies with respect to the industrial basis, regulatory status and approaches in China's medical device industry. Currently China's medical device regulatory work is faced with many problems such as imperfect legal system, outdated standard setting, low industry concentration, weak regulatory and supervisory team-building and capacity, new challenges in the wake of regulatory reform etc. The task for medical device supervision and administration is to realize in 5 years time that the production of medical device shall be basically standardized; the safety and effectiveness of medical devices shall be effectively guaranteed; medical device industry shall enjoy rapid and healthy development, as well as other goals.

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Director Yan Hui of China Pharmaceutical Newspaper awarded a Letter of Appointment to Director General Wang Baoting.

(May 10, 2011)
The recall of defective medical devices is an international practice that plays an important role for the protection of public safety in using medical devices, and a manifestation of the concept that the medical device manufacturer is the first responsible person for product quality. In order to gradually set up and improve the medical device recall system compliant with China’s actual supervision situation, the Measures for Administration of Medical Device Recall (Interim) was promulgated recently and shall go into effect as of July 1, 2011.

The Measures, comprising of 38 articles in six chapters, provides specific regulations to the administration of medical device recall from the aspects of the supervision system for medical device recall, the classification and categories of recall and the legal liabilities. The characteristics of the Measures include:

I. Gearing to international conventions in core issues. What kind of medical devices needs to be recalled is the core issue for the enactment of this "Measures". The "Measures" takes reference of the definition of defective product recall in the United States, European Union, etc. to define the product recall as: "In accordance with the required procedures, the medical device manufacturer take measures such as warning, inspection, repair, re-labeling, modifying and improving the manual, software upgrade, replacement, recall, destruction, etc. for certain defective types, models or batches of marketed products to eliminate potential defects."

II. Take reference of the overseas drug recall system to establish the medical device recall system from the aspects of the content framework, the supervision system, the classification and categories of recall and relevant legal liabilities. With respect to the regulatory system for medical device recall, the "Measures" specified in Article VIII that provincial Food and Drug Administration (Drug Administration) are the main body for medical device recall in the regulatory system. With respect to the classification and categories of the recall, Article XIII of the "Measures" classified the recall into three classes in descending order of the severity of defects in medical devices; at the same time, Article XIII classified the medical device recall into two categories: voluntary recall and mandated recall, and set up two chapters: "voluntary recall" and "mandated recall" which provide the specific content of the respective implementation procedures, supervision and management, etc. With respect to legal responsibility, the "Measures" also set punishment measures for non-compliance to the mandated recall obligations.

III. Define special regulations in consideration of the characteristics of medical device supervision, which involve diversified disciplines and a multitude of categories and varieties, and a high degree of technical complexity. The "Provisions" clearly defined the medical device recall and the handling of recalled products, in the definition of "medical device recall", in addition to the emphasis on product defects, it highlights that the medical device recall can eliminate defects not only by product recall, but also via measures such as warning, inspection, repair, re-labeling, modifying and improving the...
manual, software upgrade, replacement, recall, destruction, etc.; it also elaborates the product handling measures for recalled medical devices. Meanwhile, the "Provisions" defined the contents of the recall notice. After the recall decision is made, medical device manufacturers should immediately notify the trading enterprises, application units or inform the end-users, to control the products and prevent the recurrence of injuries. In order to increase maneuverability, the "Measures" provides the specific content of the recall notice.  

(June 16, 2011)

SFDA Defined the Classification of 166 Medical Device Products such as Hot-cold Ablation Needles of Dual-control

To meet the needs of supervision and administration of medical devices, SFDA organized relevant units and experts to define the management categories of 166 medical device products such as the hot-cold ablation needles of dual-control. Among which 16 products are subjected to the management of Class III medical devices, 70 products are subjected to the management of Class II medical devices, 23 products to the management of Class I medical devices, 9 products to the management categories depending on the circumstances, and 48 products shall not be subjected to the management of medical devices.

(June 10, 2011)

Notice on Opinion- Solicitation for "Guideline for Coronary Drug-eluting Stent Clinical Trials"

In recent years, there has been an incessant increase of coronary drug-eluting stent products applying for registration, to further reflect the scientific rationality of the clinical trials for coronary drug-eluting stents, ensure that the clinical trials are safe and effective, and guide the manufacturers to carry out clinical tests in a regulated order, SFDA Center for Medical Device Evaluation (CMDE) organized the drafting of the "Guideline for Coronary Drug-eluting Stent Clinical Trials". Through in-depth research, relevant issues in the clinical trials of drug-eluting coronary stents as stated in the Guidelines are further clarified, the Revised Draft is hereby formulated and released on the Internet for public comment as of May 26 to June 30, 2011.  

(June 1, 2011)

China-U.S. Medical Device GMP Seminar Held

From April 24 to April 30, 2011, the China-U.S. Medical Device Regulatory Forum was held in Hangzhou, Zhejiang Province. The Seminar was jointly sponsored by SFDA and the U.S. Food and Drug Administration (FDA), organized by Food and Drug Administration of Zhejiang Province, and assisted by the Medical

2011年4月24日至30日，中美医疗器械生产质量管理规范研讨班在浙江省杭州市举办，研讨班由国家食品药品监督管理局和美

Volume III 2011 3
from June 18 to 20, 2011, the Seminar for the National “863" Project- Guidelines for the Technical Review of Registration Application Information of Influenza Virus Detection Reagents, which is sponsored by Center for Medical Device Evaluation of SFDA (CMDE), was held in Fujian.

The Seminar introduced the preparations of the Guidelines as well as the advices solicited in the earlier stage, and held focus discussions on the feedback and concerned issues of the enterprises. After the Seminar, the second Draft for Comment will be formulated and released on the CMDE website, open for comments.

(May 4, 2011)

Technical Evaluation Work for Medical Devices from Jan. to Jun. in 2011

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(2011年7月4日)
Risk management information for the products

According to YY/T0316 "The application of risk management for medical devices", risk analysis should be made to elaborate the risk control measures taken for all aspects of the contact lens care products life cycle: raw materials, production process, packaging, sterilization, transportation, storage, use, etc., from the perspectives of energy hazards (if involved), biological hazards, environmental hazards, the hazards of relevant usages, and hazards caused by malfunction, maintenance and the aging of products etc.

Standards for the registered products

According to the requirements of "Provisions for the standard management of medical device" (Interim), the registered products standards should be consistent with national standards, industry standards and relevant laws and regulations. On this basis, the production enterprise should, taking into account the product features, refer to relevant requirements of "Guidelines for the application information of product registration for passive implantable medical devices" and establish technical requirements to ensure the safety, effectiveness and quality controllability of the products. The technical requirements and test methods in the standards for registered products should undergo validation.

Registration tests for the products

Under normal circumstances, registration tests should be conducted on selected product specification with the highest risk (May not to be limited to one specification) according to the stability of the product (may refer to YY0117.6 "Ophthalmic optics contact lens care products Part 6: Guidelines for the determination of validity period"). If the validity periods of different specifications of the same product are diversified, the different specifications should be tested separately.

Clinical trial data of the products

For registration application programs that call for clinical trials in China as required by the "Provisions for Medical Device Registration", the clinical trials should be consistent with the "Provisions for the Medical Device Clinical Trials" issued by SFDA, and other relevant laws and regulations, the clinical trials programs should be developed and implemented while referring to the Guidelines.

The clinical data for contact lens care products should evaluate and recognize the clinical safety, efficacy of contact lens care products; researches should be conducted on whether the contact lens care products have provided safe and effective care and maintenance for their commensurately difference of contact lens, the compatibility of lens care products with the lens and the impact on the eyes; clinical trials observations should be conducted for newly developed functions of contact lens care products.

1. Scope for application

Applicable for the cleaning, disinfection, rinsing, soaking, preservation of contact lens. The applicable type of contact lens and functions of care products should be clearly defined in accordance with the specific features of the reported products.

2. Clinical trial programs

The design of clinical trials should focus on the following considerations:

(1) Set a reasonable control group

Currently all contact lens care products in China applying for entry into the market and in need of clinical trials as required by laws and regulations must set a control group in clinical trials, and the control products should be similar

(To continue)
products that have been approved for marketing in China, and the applicable lenses for the control group and test group should be the same. For innovative products with no similar products for clinical trials, routine lens care products and methods should be used in clinical trials as a control.

(2) Evaluation on the cases of clinical trials (sample size)

The assessment of the effectiveness, safety of contact lens care products should adopt common clinical evaluation criteria. The duration of clinical trials should be no less than 3 months, each case for evaluation should have complete data for both eyes, the final total samples completed in clinical trials should be no less than 120 patients, with the 1:1 test-control ration, the test group shall contain at least 60 cases. In accordance with the existing "Provisions for medical device clinical trials", the clinical trials should be held in more than two medical institutions. The test group and control group should be not less than 120 patients, and the test group shall contain at least 60 cases. In accordance with the existing "Provisions for medical device clinical trials", the clinical trials should be held in more than two medical institutions.

3. The test group and control group should take uniform inclusion standards and exclusion criteria, the specific content of which shall be determined by specific discussions and decision made by the parties responsible for clinical trials.

4. Clinical observation items and assessment index for routine curative effect

(1) The refractive state: uncorrected visual acuity, best corrected visual acuity, refraction. We can use the Chinese standard logarithmic visual acuity chart to examine and record (in decimals or logarithms) the uncorrected visual acuity and a variety of corrected distance vision and near vision of the volunteers. The refractive changes of the subjects before and after wearing glasses should be provided (spherical degree and cylinder degrees).

(2) Eye condition: periodic follow-ups are required for the observation of ocular changes in the period of clinical trials, including: the tear film, conjunctiva, cornea, anterior chamber, lens, retina, intraocular pressure etc., meanwhile the clinical complications incidences should be closely monitored and recorded, during the study period and concurrent records the of disease, the frequency of follow-ups shall be designed and determined by the unit responsible for the trails and in principle, be no less than three times.

(3) Fitting status of the contact lens: The positions (center position) in the ocular surface, tightness, mobility, and fluorescent staining (applicable for rigid, air permeable contact lens) of the lens are required to be observed in first wearing and periodic follow-up, and to evaluate and record their grades.

(4) Test lens care solution and the lens: in periodic follow-ups, observe the stained status of the lens, whether there is precipitation, deformation, discoloration, rusty spots, scratches, breakage etc., and whether the lens care solution has turbidity, impurities, and precipitation.

(5) Safety Evaluation:

① Ophthalmological adverse reaction
② Ocular complications diagnosed by the doctors
③ Abnormal changes in the lens

The conventional evaluation index for clinical efficacy of the Contact lens care products can be found in Appendix I and II.

5. Follow-up visit schedule and methods

Follow-ups shall be conducted at the First week, First month and Third month respectively after the application (more frequent observations shall be conducted according to the specific circumstances), the effectiveness, safety, comfortability etc. of contact lens care products can be assessed in the follow-ups (details of the follow-ups can be found in Appendix III). (Mar. 24, 2001)

目前凡在我国申请上市、按法规需要进行临床试验的接触镜护理产品，进行临床试验时均应设立对照组。对照产品应是我国已经批准上市的同类产品。对照组与试验组的选用镜片应相同。对于临床上无同类产品的创新型产品，应采用临床常规的镜片护理产品及方法作为对照。(2) 临床试验病例数（样本量）评价

接触镜护理产品的有效性、安全性的评估均应采用临床前通用的比例标准。临床试验持续时间须不少于3个月。每个评价病例应是完整的双眼数据，临床试验最终完成样本容量不少于120例，按1：1设置对照组、试验组不少于60例。根据现《医疗器械临床试验规定》，临床试验应当在两家以上（含两家）医疗机构进行。

3. 试验组和对照组需采用统一的入选标准和排除标准。其标准的具体内容由临床试验负责单位具体讨论决定。

4. 临床试验观察项目及常规疗效评价指标

(1) 角膜状态：裸眼视力、最佳矫正视力、角膜度。其中视力可利用我国标准对数视力表检查患者的裸眼及各种矫正视力，近视力并进行记录（小数或对数），应提供受试者戴镜前后的屈光度变化（球镜度及柱镜度）。

(2) 眼部情况：在临床试验期间要求定期随访观察眼部的变化，包括：泪液、角膜、角膜、前房、晶状体、眼底、眼压等。在试验期间需严密监控并记录临床并发症的发生。随访次数由试验负责单位设定确定，原则上不能少于三次。

(3) 接触镜配适状态：初次配戴及定期随访中观察镜片在眼表的位置（中心定位）、松紧度、活动度、荧光染色（硬性透气性接触镜适用），并评价与记录其等级。

(4) 测试护理液和镜片：定期随访中观察镜片的污染情况，观察镜片有无沉淀、变形、变色、锈斑、划痕、破损等，护理液有无混浊、杂质、沉淀等。

(5) 安全性评价：
① 受试者的眼部不良反应
② 医生诊断的眼部并发症
③ 镜片的异常改变

目前接触镜护理产品的临床常规疗效评价指标可参见附录I和附录II。

6. 随访时间点及方法

分别于使用后1周、1个月、3个月进行随访（结合试验具体情况进行频率的观察时间），在随访中对接触镜护理产品的有效性、安全性、舒适性等方面进行评估（临床内容可参见附录III）。 (2011年3月24日)
The Second International Medical Device Regulatory Forum Held in Beijing

From June 8 to June 11, 2011, the Second International Medical Device Regulatory Forum & the Medical Device Pre-Market Review Workshop, which was organized by China Center for Pharmaceutical International Exchange (CCPIE), was held in Beijing. SFDA Deputy Commissioner Bian Zhenjia attended the opening ceremony and delivered an important speech.

In his opening speech, Deputy Commissioner Bian Zhenjia expressed his sincere congratulations to the opening of the Forum, and his warm welcome to the participants home and abroad. Deputy Commissioner Bian introduced the establishment, constant development and improvement of China’s medical device supervision and administration system, emphasizing that while drawing upon the advanced experience of the Western world, we should formulate in a realistic manner the supervision and administration of medical devices. About 800 domestic and foreign representatives attended the forum and Pre-Market Review Workshop.

The forum is co-organized by: United States Advanced Medical Technology Association (AdvaMed), the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), China Medical Device Industry Association (CAMDI), European Union Committee of Medical Device Industry (Eucomed), Japan Industrial Association of Radiographic Medical Systems (JIRA) and the European Diagnostic Equi pment Manufacturers Association (EDMA).

Meeting Brief

China’s Medical Device Trade Statistics in the "Eleventh Five-Year Plan" Period and the outlook in the future

In the "Eleventh Five-Year Plan" period, China's medical device industry has achieved sustained, stable growth. In the "Twelfth Five-Year Plan" period, with the enhanced China's overall technological level and the wide application of new materials, new technology, China's medical device products shall transfer from low & medium grades to high-end products, independent innovation and R & D of individual products will have breakthroughs, the overall size and efficiency of the industry will be boosted, the enterprises will shall enjoy further development with reduced costs and sustainable effective market competitiveness.

The international competitiveness shall be further strengthened

In the "Twelfth Five-Year Plan" period,
medical dressing products will become the world’s mainstream products.

**Rapid trade growth in emerging markets**

Over the past five years, the medical devices trade of China with her three major trade partners: the EU, U.S. and Japan continued to grow and maintain a stable growth rate. In the next five years, the trade between China and the emerging economies as well as the developing countries will achieve a rapid growth, the markets in ASEAN, India, Brazil, South Africa, Russia, Africa, Middle East and other countries and regions will become new growth points.

**Forming a core business pattern**

In the next five to ten years, China’s medical device industry in the world medical device trade market will become more closely associated, which is bound to have a tremendous impact on China’s medical device manufacturing processes, new material application, research and development level, and marketing network, and will promote the transformation of China’s medical device products from low-end products to high value-added products. Guangdong, Zhejiang, Jiangsu, Shanghai, Beijing will continue to lead the development of the industry and become the cluster areas of industrial advantages. (June 8, 2011)

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China will foster a number of internationally competitive medical device enterprises and a products system with independent intellectual property rights, to lay a solid foundation for China to become a superpower in medical devices production.

In the next five years, China’s annual export of medical products is expected to exceed $31.5 billion, of which, the market share for sub-high-end medical devices and high value-added products will top two-thirds. Foreign trade share of China’s medical device industry in world medical device trade market is expected to reach 10% to 12%, China is to become the world’s second largest medical device trade market of the world, to develop into the dominant area of the world medical device market in world medical device trade market.

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**International competitiveness further strengthened**

“Eleventh Five-Year” period, China’s medical devices with high value-added products from low-end products in 2010, China’s medical devices proportion in the world’s main products has reached 10% to 12%, China is expected to become the world’s mainstream products in the world medical device market.

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**New market rapid growth**

In the next five years, China’s medical device export market share of the world’s main products will exceed $100 million, the China’s medical devices trade market is expected to reach 10% to 12%, China is to become the world’s second largest medical device trade market, and maintain a stable growth rate. In the next five years, China’s medical devices trade market will become the world’s mainstream products in the “Eleventh Five-Year” Period. (Part I)
Analysis of China's Medical Electronics Market in 2011

In recent years, the emerging industry of medical electronics has witnessed a rapid rise, especially in the Chinese market. As China gradually becomes an aging society, the demand for medical electronic products is also growing. According to ISUPPLI data, in 2010, China's annual medical electronics market volume amounted to $5.791 billion, a 44% growth compared with that of 2009. It is anticipated that in 2011, China's annual medical electronics market will total $7.22 billion, up 25% compared with that of 2010.

In 2013, the medical electronics market in China is anticipated to top $10 billion, reaching $10.056 billion. Among the sub-applications of market segmentation, the imaging devices still constitute the largest market share, followed by consumer medical devices. In 2011, the above two major areas of the market are expected to enjoy rapid growth of 35%, 30% respectively. With a growth rate of 42%, the monitoring devices enjoy the fastest growth.

Bariatric Surgical and Procedural Interventions in the Treatment of Obese Patients with Type 2 Diabetes

Obesity and type 2 diabetes are serious chronic diseases associated with complex metabolic dysfunctions that increase the risk for morbidity and mortality. Faced with the escalating global diabetes crisis, health care providers require as potent an armamentarium of therapeutic interventions as possible. In addition to behavioural and medical approaches, various types of surgery on the gastrointestinal tract, originally developed to treat morbid obesity (“bariatric surgery”), constitute powerful options to ameliorate diabetes in severely obese patients, often normalising blood glucose levels, reducing or avoiding the need for medications and providing a potentially cost-effective approach to treating the disease.

Bariatric surgery is an appropriate
treatment of obese patients with type 2 diabetes.

2011年中国医疗电子市场分析

近年来，医疗电子作为一个新兴产业正在迅速崛起，尤其是在中国市场。随着中国逐步迈进老龄化社会，对医疗电子产品的需求也越来越大。据isuppli提供的数据显示，2010年，中国医疗电子全年市场总额达57.91亿美元，较2009年市场增长了44%。预计2011年，中国医疗电子全年市场总额将达到72.2亿美元，较2010年增长25%。预计在2013年，中国的医疗电子市场总额突破100亿美元大关，达到100.56亿美元。

在细分应用领域中，影像设备仍占最大市场份额，其次是消费类医疗设备。预计2011年，这两大领域的市场份额分别以35%、30%的增长率高速增长，成长最快的为监护设备，将以42%的增长率成长。

减肥手术和手术介入
治疗2型糖尿病肥胖患者

肥胖症和2型糖尿病是与复合代谢障碍关联的严重慢性疾病，复合代谢障碍增大了发病和死亡的风险。面对全球逐渐上升的糖尿病危机，卫生保健提供者需要一种尽可能有效的介入治疗器械。除行为途径和医疗途径外，对胃肠道进行各种手术（原本目的是治疗病态肥胖症（“减肥手术”））。成为严重肥胖患者改善糖尿病的有力选择。通常可使血糖水平正常化，减少或避免药物治疗的必要性，提供了一种潜在的经济的治疗途径。
access to attractive caloric-dense foods acting on susceptible genotypes. The most recent global predictions by the International Diabetes Federation (IDF) suggest that there are 285 million people with diabetes currently worldwide. This is set to escalate to 438 million by 2030, with a further half billion at high risk. Diabetes is looming as one of the greatest public health threats of the 21st century.

Type 2 diabetes is a risk factor for vascular and neurovascular damage: both micro-vascular (retinopathy; nephropathy and neuropathy) and macro-vascular (premature and more extensive cardiovascular-, cerebro- and peripheral vascular disease). Premature mortality and morbidity from diabetes result from such complications. The disease results from inadequate insulin production and action and results in hyperglycaemia, but is also associated with multiple other dysfunctions involving lipid metabolism; oxidative stress; inflammation and haemato-rheology. In addition, obesity, by itself, generates similar cardio-metabolic dysfunction.

What is the link between obesity and type 2 diabetes?

Type 2 diabetes is an heterogeneous disorder, and, while its causes have yet to be fully explained, obesity is considered the primary risk factor. It has been estimated that the risk of developing type 2 diabetes is increased 93-fold in women and 42-fold in men who are severely obese rather than of healthy weight15. A small proportion of people with type 2 diabetes, approximately 15% in populations of European origin, are not overweight6.

In the short term, even modest weight loss in people with type 2 diabetes who are overweight or obese is associated with improvements in glycaemic control and associated conditions such as hypertension and dyslipidaemia. However, there is strong evidence that significant weight loss achieved by using lifestyle and medical methods by obese, particularly severely obese, people is modest and rarely sustained, particularly in the severely obese.

Why should bariatric surgery be considered for people with type 2 diabetes and obesity not achieving recommended treatment targets with medical therapies, especially when there are other major comorbidities. Surgery should be an accepted option in people who have type 2 diabetes and a BMI of 35 or more. Surgery should be considered as an alternative treatment option in patients with a BMI between 30 and 35 when diabetes cannot be adequately controlled by optimal medical regimen, especially in the presence of other major cardiovascular disease risk factors. In Asian, and some other ethnicities of increased risk, BMI action points may be reduced by 2.5 kg/m2. Clinically severe obesity is a complex and chronic medical condition. Societal prejudices about severe obesity, which also exist within the health care system, should not act as a barrier to the provision of clinically effective and cost-effective treatment options. Strategies to priorities access to surgery may be required to ensure that the procedures are available to those most likely to benefit. Available evidence indicates that bariatric surgery for obese patients with type 2 diabetes is cost-effective. Bariatric surgery for type 2 diabetes must be performed within accepted international and national guidelines. This requires appropriate assessment for the procedure and comprehensive and ongoing multidisciplinary care, patient education, follow-up and clinical audit, as well as safe and effective surgical procedures. National guidelines for bariatric surgery in people with type 2 diabetes and a BMI of 35 or more need to be developed and promulgated. The morbidity and mortality associated with bariatric surgery is generally low, and similar to that of well-accepted procedures such as elective gall bladder or gall stone surgery. Bariatric surgery in severely obese patients with type 2 diabetes has a range of health benefits, including a reduction in all-cause mortality.

The global prevalence of type 2 diabetes is rising dramatically, driven by an “obesogenic” environment that favours increasing sedentary behaviour and easier access to attractive caloric-dense foods acting on susceptible genotypes. The most recent global predictions by the International Diabetes Federation (IDF) suggest that there are 285 million people with diabetes currently worldwide. This is set to escalate to 438 million by 2030, with a further half billion at high risk. Diabetes is looming as one of the greatest public health threats of the 21st century.
considered in algorithms for treating obese type 2 diabetes?

Type 2 diabetes is a progressive disease and the usual natural history is of progressive loss of insulin secretory capacity over time and the need for intensification of therapy and polypharmacy. Arresting this progression is a formidable therapeutic challenge. Treatment for type 2 diabetes must also include active management of all cardiovascular risk factors (hypertension, dyslipidaemia, smoking and inactivity) but glycaemic control is very important – and not just for prevention of microvascular disease. Years of improved glycaemic control continue to deliver reduced risk of macrovascular disease and mortality over subsequent years.

A major problem for managing type 2 diabetes is the need for continuous monitoring and intensification of therapies by adding new agents in increasing doses over time. The ADA and EASD consensus statement recommends that an HbA1c of 7% is a call to action. Some national guidelines, such as those from UK’s NICE, support more vigorous intensification of glycaemic therapies in early stages of diabetes. NICE used HbA1c ≥ 6.5% to increase from monotherapy but ≥7% for increasing to triple therapies and beyond. This is very important. In one trial that randomised people with type 2 diabetes and existing cardiovascular disease to very intensive management targeting HbA1c <6.5%, mortality was higher in the intensive group, driven by deaths in those people who failed to show HbA1c improvement as treatment was intensified. This should not be taken to mean people with early type 2 diabetes should be treated less vigorously as the legacy effect of early intervention is considerable.

A critical issue has been the rate at which health care professionals escalate therapies. Current approaches that rely on loss of glycaemic control and on intensifying lifestyle or other time consuming measures set clinicians up for failure to achieve targets.

It may be possible to achieve much more in terms of complication prevention – or even possibly slowed rate of progression – if treatments are started and intensified early. There have even been suggestions of starting polypharmacy at diagnosis but there is limited current evidence to demonstrate the efficacy of this.

Apart from the side effect profiles and suboptimal deployment of existing medical diabetes therapies, there remain issues around patient engagement in many aspects of their lives. Very few clinical services routinely provide psychological support to encourage life-long engagement in self-care.

The continuing morbidity and mortality in persons with diabetes is a sign that the answer as to the best management for type 2 diabetes in terms of maximising metabolic control is still elusive. Given this scenario, the option of bariatric intervention needs to be considered in appropriately selected individuals.

What is a successful outcome of bariatric surgery for a person with type 2 diabetes?

Improved patient health would be recognised by individualised optimisation of metabolic state which involves normalisation of metabolic state, ie:

- HbA1c ≤ 6%
- no hypoglycaemia
- total cholesterol < 4 mmol/l; LDL cholesterol < 2 mmol/l
- triglycerides < 2.2 mmol/l
- BP < 135/85 mmHg
- >15% weight loss
- With reduced medication from pre-operated state or without other medications (where medications are continued, reduced doses from pre-surgery with minimal side effects would be expected)

A substantial improvement in metabolic state may be defined as:

- Lowering of HbA1c by > 20%
- LDL < 2.3 mmol/l
- BP < 135/85 mmHg

Factors.据估计，体重严重超过健康体重的女性和男性，患2型糖尿病的风险分别增加93%和42%。少数2型糖尿病患者——欧洲血统人群中约15%，并不过重。从短期来看，甚至超重或肥胖的2型糖尿病患者适度减重，也会与血糖控制和相关条件(例如高血压和脂代谢紊乱)的改善有关。然而，有力证据表明，肥胖患者，特别是严重肥胖患者，通过生活方式和药物疗法获得显著的体重减轻是不大的且很难能够维持，特别是对于严重肥胖患者。

为什么在治疗2型糖尿病时应考虑减肥手术?

2型糖尿病是一种进行性疾病，一般自然史为胰岛素分泌能力时随时间发生进行性损害，治疗和反复用药的必要加强。捕捉这种进行性是一个强大的治疗难题。2型糖尿病的治疗还必须积极控制所有心血管风险因素(高血压、脂代谢紊乱、吸烟)。但是血糖控制是非常重要的，并且不仅仅是为防止微血管疾病。多年持续进行改善性血糖控制，可减少随后几年发生大血管疾病和死亡的风险。

控制2型糖尿病的主要问题是需要持续监测并随增加剂量，以强化治疗效果。ADA和EASD共识声明建议，糖化血红蛋白(HbA1c)7%是作用界限，一些国家指导原则，例如英国的NICE，支持在糖尿病早期阶段进行更有力的血糖控制强化疗法。NICE采用HbA1c ≥ 6.5%作为从单一疗法升级的作用界限，采用≥7%作为升级为三联疗法和更高级疗法的作用界限。这是非常重要的。在一项试验中，使患者2型糖尿病既有关心血管疾病的患者随机分为正常化控制，以HbA1c <6.5%为目标，强化组的死亡率要高，这是由随着治疗被强化，不能显示HbA1c改善的患者死亡导致的。这一点不应用来说明“2型糖尿病患者的治疗强度应比早期介入的传统效应要小”是值得考虑的。

关键问题一直是卫生保健专业人员升级疗法的比率，当前方法依赖于血糖失去控制，以及依赖于强化生活方式或其他时间消耗措施，使得临床医师不能达到目标。

如果治疗开始并且提前进行强化，在并发症预防方面可能会获得更多，甚至可能出现进行率变慢的情况。甚至有人建议在诊断时就开始采用多药疗法，但是目前能够证明这样做效力的证据有限。

除副作用，以及现有糖尿病药物疗法欠佳外，在患者生活的许多方面，围绕患者参与仍有许多问题。极少数医疗单位常规提供心理支
With reduced medication from the pre-operated state
The above definitions, with a focus on diabetes, complement broader success

References


Notes: • All Chinese information in Newsletter extracted from Newspapers and Internet. All English articles are the translations from the Chinese version.

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